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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/188,051	11/06/1998	BRET A. SHIRLEY	5784-25	3829

7590 08/18/2003

Chiron Corporation  
Intellectual Property Dept.  
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EXAMINER

KAM, CHIH MIN

ART UNIT

PAPER NUMBER

1653

DATE MAILED: 08/18/2003

35

Please find below and/or attached an Office communication concerning this application or proceeding.

1

1

# Office Action Summary

Application No.

09/188,051

Applicant(s)

SHIRLEY ET AL.

Examiner

Chih-Min Kam

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 18 June 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 29-48 and 85-112 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 29-48 and 85-112 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

## DETAILED ACTION

### *Status of the Claims*

1. Claims 29-48 and 85-112 are pending.

Applicants' amendment filed on June 18, 2003 (Paper No. 34) is acknowledged, and applicants' response has been fully considered. Claims 29, 41, 42, 46, 85, 94, 95, 99, 101, 108 and 109 have been amended. Thus, claims 29-48 and 85-112 are examined. A telephone call was made to Attorney, Leslie Henry on August 12, 2003 to resolve the issue on Obviousness Type Double Patenting, however, the Attorney cannot be reached at this time.

### *Oath/Declaration*

2. A substitute declaration in compliance with 37 CFR 1.67(a) filed September 17, 2002 is acknowledged.

### *Rejection Withdrawn*

#### *Claim Rejections - 35 USC § 103*

3. The previous rejection of claims 29-44, 46-48, 85-97 and 99-111 under 35 U.S.C. 103(a) as being unpatentable over Florin-Robertsson *et al.* (WO 94/15584) taken with Ron *et al.* (U.S. Patent 5,597,897), is withdrawn in view of applicants' response at pages 11-15 in Paper No. 34.

#### *Claim Rejections-Obviousness Type Double Patenting*

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground

Art Unit: 1653

provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 29-48 and 85-112 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 5, 10-14, 16, 17, 18 and 20 of copending Application No. 09/187,661.

Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 29-48 and 85-112 in the instant application disclose a composition having a pH of 5.5 or greater, comprising IGF-I or a biologically active analog thereof having an amino acid sequence which shares at least 70% sequence identity to human IGF-I at a concentration of about 12 mg/ml to about 200 mg/ml, and at a temperature of about 4 °C, and a solubilizing compound comprising a guanidinium group, wherein the solubilizing compound is in an amount sufficient to make IGF-I or analog thereof soluble at a concentration of about 12 mg/ml to about 200 mg/ml, and at a temperature of about 4 °C. This is obvious in view of claims 1, 2, 5, 10-14, 16, 17, 18 and 20 in the copending application which disclose a low salt-containing aqueous composition comprising human IGF-I or a biologically variant thereof in a concentration of at least about 250 mg/ml and a pH greater than about 5.0, wherein the variant is a polypeptide which has at least 80% sequence identity to human IGF-I. Since the low salt-containing composition can be a composition containing a salt such as arginine, guanidine·HCl or other arginine compounds in an amount that makes IGF-1 or its analog more soluble at higher concentration and at about 4 °C, thus, both sets of claims encompass a low salt-containing (e.g., arginine) aqueous composition comprising human IGF-I or a biologically variant thereof at a

Art Unit: 1653

concentration of about 250 mg/ml and a pH greater than about 5.5, wherein the variant is a polypeptide which has at least 80% sequence identity to human IGF-I. Thus, claims 29-48 and 85-112 in present application and claims 1, 2, 5, 10-14, 16, 17, 18 and 20 in the copending application are obvious variations of a low salt-containing (e.g., arginine) aqueous composition comprising human IGF-I or a biologically variant thereof at a concentration of about 250 mg/ml and a pH greater than about 5.5, wherein the amount of arginine compound that makes IGF-I or its analog more soluble at about 4 °C.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

In response, applicants indicate the claimed invention is directed to a composition having a pH of about 5.5 or greater that comprises biologically active IGF-1 or analog thereof at a concentration of about 12 mg/ml to about 200 mg/ml at a temperature of about 4 °C, while the claims of 09/187,991 are directed to low-salt containing aqueous composition that comprise biologically active IGF-1 or analog thereof at a concentration of at least 250 mg/ml and which have a pH greater than about 5.0; the specification of 991' application teaches suitable solubility enhancer is a compound that includes a guanidium group, which has been removed from the solution in order to precipitate out the IGF-1 protein or variant thereof, thus, the composition recited in the claims of 991' application do not contain the solubilizing compound in the manner as the instant claimed composition, where the IGF-1 or variant thereof would be present in its soluble form at a concentration of about 12 mg/ml to about 200 mg/ml; and claims 41-43, 94-96, and 108-110 of the present invention which include the limitation with upper concentration of about 200 mg/ml were not subject to this rejection in the Office Action (Paper No. 32), thus, the

Art Unit: 1653

present claimed composition is patentably distinct from the composition claimed in 991' application. The response has been fully considered, however, the argument is not found persuasive because the composition comprises IGF-1 or variant thereof at a concentration of about 12 mg/ml to about 200 mg/ml, and the specification has not defined the concentration range for "about", thus, the upper limit of the concentration can be 250 mg/ml. Moreover, the claims of 991' application recites a low salt-containing aqueous composition comprising human IGF-I or a biologically variant thereof in a concentration of "at least about" 250 mg/ml, which indicates the concentration of IGF-1 or variant thereof can be lower than 250 mg/ml in terms of "about", and the low salt can be low arginine concentration in the aqueous composition. Regarding the issue that the claimed composition of 991' application do not contain the solubilizing compound in the manner as the instant claimed composition, since the claims of 991' application do not recite the limitation that indicates the difference between these two applications, they will read on the claims of instant application. Claims 41-43, 94-96, and 108-110 which were not included in the rejection in the previous Office Action are included in this rejection because of interpretation on the term "about".

### ***Conclusion***

5. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (703) 308-9437. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, Ph. D. can be reached on (703) 308-2923. The fax phone numbers

Application/Control Number: 09/188,051

Page 6

Art Unit: 1653

for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D. *CMK*  
Patent Examiner

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August 12, 2003

*Christopher S. F. Low*

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